IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

IN RE: ETHICON, INC. PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	**Master File No. 2:12-MD-02327** **MDL No. 2327**
THIS DOCUMENT RELATES TO ETHICON WAVE 1 MOTIONS	**JOSEPH R. GOODWIN** **U.S. DISTRICT JUDGE**

MEMORANDUM IN SUPPORT OF MOTION TO EXCLUDE CERTAIN GENERAL OPINIONS OF JERRY BLAIVAS, M.D.

Defendants Ethicon, Inc. and Johnson & Johnson (hereinafter "Defendants") submit this memorandum in support of their motion to exclude certain general opinions of Jerry G. Blaivas, M.D., with respect to the cases set forth in Exhibit A to Defendants' accompanying motion.

INTRODUCTION

Dr. Blaivas is a New York urologist, who has experience treating patients with stress urinary incontinence ("SUI") and pelvic organ prolapse ("POP") and who has experience removing sling systems. Ex. A to Ex. B, TVT Expert Report, CV. He is an advocate of native tissue repairs to treat POP and the use of autologous slings to treat SUI. Those slings are made of a woman's own tissues and implanted in a surgery that, unlike mesh surgery for SUI, requires general anesthetic, more invasive surgery, and the use of tension.

Dr. Blaivas intends to provide general opinions about TVT, TVT-O, TVT Secur, TVT Exact and TVT Abbrevo (collectively "the TVT Devices"), used to treat SUI, as well as Prolift, which is used to treat POP. Ex. B-G, Expert Reports.[1] As set forth below, the Court should preclude Dr. Blaivas from testifying about matters that are beyond his expertise, that are

[1] Because most of Dr. Blaivas's opinions about the TVT Devices are the same, citations in this brief are generally limited to his TVT report (Ex. B).

unreliable, that are irrelevant, and/or that are otherwise improper. He cherry-picks data, cannot cite support for his opinions in the medical literature, and fails to explain contradictions in articles he has helped write. In other words, he is an advocate who applies a lower standard to his testimony than he applies to either his medical practice or to his role as an scholar, and for that reason should not be allowed to testify. *See Wilkerson v. Boston Scientific Corp.*, 2015 WL 2087048, at *15 (S.D. W. Va. May 5, 2015) (excluding Dr. Blaivas opinions).

LEGAL ARGUMENT

Defendants incorporate by reference the standard of review for *Daubert* motions set forth by the Court in *Huskey v. Ethicon, Inc*., 29 F. Supp. 3d 691, 701 (S.D.W. Va. 2014).

I. The Court should preclude Dr. Blaivas from testifying that TVT Devices are not safe in the treatment of SUI.[2]

Dr. Blaivas admits that TVT has been a "gold standard" in the medical profession for the surgical treatment of SUI, that it has been studied more than any other device or procedure for this intended use, and that more physicians use synthetic slings to treat SUI than other methods. Ex. H, Sept. 2015 Dep. 72:8-13, 78:17-24, 100:23-101:8, 173:16-23. Indeed, Dr. Blaivas helped formulate SUI guidelines for the American Urological Association ("AUA"), which concluded that TVT and other polypropylene midurethral slings are a suitable surgical option for the treatment of SUI, and he recently co-wrote an article finding that the mesh in TVT Devices is the "optimal" type of mesh to be used. (*Id.* at 98:7-99:20, 153:16-21; Ex. 4 thereto, p. 11; Ex. 5 thereto). Yet, he now claims that TVT Devices' complication rates of are high and that they are unsafe. As set forth below, Dr. Blaivas's opinions are unreliable and should be excluded.

A. Dr. Blaivas has conceded that whether the complications are the result of surgeon error or characteristics of the mesh is unknown.

[2] If the Court concurs with Defendants on this argument in Section I, it need not consider Section II-V with respect to Defendants' TVT Devices.

In a 2013 article published by *The Journal of Urology*, Dr. Blaivas and his co-authors state that "[t]he etiology of mesh sling complications is a matter of conjecture" and that surgeons may be to blame. Ex. I, *et al*., "Salvage Surgery after Failed Treatment of Synthetic Mesh Sling Complications," *The Journal of Urology*, v. 190, p. 1284 (2013). To the extent that he departs from that opinion now, Dr. Blaivas is applying standards in this litigation different than the standards that he applies in his medical practice. *See* Ex. J, Dec. 15, 2014 Dep. 391:14-392:12. This is strictly forbidden by *Daubert*. *See Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 152 (1999) (stating that an expert must "employ[] in the courtroom the same level of intellectual rigor that characterizes the practice of an expert in the relevant field").

For these same reasons and based on this same article, this Court recently precluded Dr. Blaivas from testifying that polypropylene mid-urethral slings are unsafe for surgically treating SUI. *Wilkerson v. Boston Scientific Corp.*, 2015 WL 2087048, at *15 (S.D. W. Va. May 5, 2015). The Court noted that Dr. Blaivas admitted that he employs a different standard for medical literature than he employs when providing opinions in litigation. *Id.* (citing Ex. J). Based on Dr. Blaivas's admissions, the Court should preclude him from providing such testimony in these cases.

B. Dr. Blaivas's opinions about TVT Devices are premised on an unreliable assessment of complications and complication rates.

A separate reason that the Court should preclude Dr. Blaivas from testifying that TVT Devices are unsafe is because, as set forth below, his opinions about TVT Device complications and complication rates are unreliable.

1. "Unreliable Minimum 12.5% Complication Rate Opinions"

Dr. Blaivas apparently intends to testify that TVT Devices have a minimum 12.5% complication rate based on a 2015 review article that he co-wrote with Dr. Vladimir Iakovlev

and others titled "Safety considerations for synthetic sling surgery." Ex. H, Sept. 2015 Dep. 118:19-120:4; Ex. 4 thereto, pp. 6, 21. Therein, Dr. Blaivas and his colleagues concluded that "a minimum of 12.5% of women who undergo [synthetic midurethral sling surgery] have a serious adverse event and/or surgical failure." *Id.* The Court should find that this opinion is unreliable for many reasons.

When asked very recently about his opinion concerning complication rates in the *Huskey* case, Dr. Blaivas conceded that it was impossible for him to accurately opine about synthetic mesh complication rates. As set forth in this Court's ruling in that case:

> I **FIND** that Dr. Blaivas's opinions on complication rates are unreliable. In discussing complication rates, Dr. Blaivas did not explain his methodology and admitted that it was impossible to calculate an accurate complication rate:
>
> > A: I mean, just to be fair, I mean, I haven't said you should never use it. I mean, look, my contention is that this information should be available not just to the experts but to the implanting doctors worldwide and to the patients.
> >
> > And *I can't tell you if it's 1 percent or 9 percent.* I can't tell you that it's going to—I hope it doesn't, maybe after ten years it will be 20 percent, or maybe some of them will get better. I don't know. All I can tell you right now is that it's very clear to me that these kinds of things happen, at the very least, in the single digit percent rate.
>
> (Blaivas Dep. [Docket 214–2], at 189:11–190–4). In light of this testimony, Dr. Blaivas's opinions regarding complication rates are **EXCLUDED.**

Huskey v. Ethicon, Inc., 29 F. Supp. 3d 691, 721 (S.D. W. Va. 2014) (emphasis added). Given this admission, Dr. Blaivas may not, merely a year later, purport to be certain about TVT complication rates. The Court should apply its ruling in *Huskey* to this case.

Dr. Blaivas's 2015 review article does not change the result in *Huskey*, because there is no indication that the 12.5% complication rate estimated in that article has any semblance of reliability. That article (headed by a team of Plaintiffs' experts in this mesh litigation) is

equivocal and lacks reliability on its face. For instance, the review article does not even set forth the methodology by which the 12.5% figure was derived.

In his deposition, Dr. Blaivas was unable to explain the calculation, dodging the question by vaguely stating that "we calculated it a few different ways" without specifying any of the "ways" that it was calculated. Ex. H, Sept. 2015 Dep. 227:22-229:24. In fact, the article, itself, laments that "[t]he problem, simply stated, is that no well-controlled long-term studies with published results currently exist, nor do any good registries in this area," and its conclusion conciliatorily quotes Carl Sagan's quip that "absence of evidence is not evidence of absence." Ex. 4 to Sept. 2015 Dep. (Ex. H), pp. 5, 21. In *Sanchez v. Boston Scientific Corp.*, 2014 WL 4851989, at *14 (S.D. W. Va. Sept. 29, 2014), this Court excluded an expert's opinions about complication rates, because the expert "'assume[s] the worst-case scenario' and errs on the side of opining as to a higher complication rate to better protect a patient." The Court should similarly find that Dr. Blaivas's 12.5% calculation is unreliable due to unsound methodology.

Moreover, Dr. Blaivas's review article cherry picks the data, failing to take into account long-term studies finding TVT complication rates to be much lower. At Table 1 of the article, the authors collected 11 studies purportedly meeting the criteria for inclusion. Ex. 4 to Sept. 2015 Dep., (Ex. H) pp. 3, 21; Ex. H, Sept. 2015 Dep. 84:4-15, 107:18-19. When asked whether it would "concern [him] if there were more than ten other TVT retropubic studies with five-years duration or more that you did not include in that table in [his] review article," Dr. Blaivas conceded that he would "want to see them." *Id*. at 120:7-11. During his deposition, Dr. Blaivas was confronted with long-term studies that were not identified in Table 1, that met the criteria of the report, and that Dr. Blaivas admitted were "very good" and/or "well done." *Id.* at 109:7-113:22, 179:1-4; 180:9-12, 185:13-189:4, 192:12-195:7, 198:24-206:22, 213:9-10; 367:9-386:6;

Ex. 12-14, 25-27 thereto. In fact, the report omitted *20* studies which, perhaps not surprisingly, reflect a complication rate well lower than 12.5%.

Dr. Blaivas could not explain why these studies were not cited in the table, he agreed that it was "painful" for him not to know, during a break in the deposition he called a co-author to try to figure out why they were excluded, and finally acknowledged that he and his co-authors committed an "error" by excluding them. Ex. H, Sept. 2015 Dep. 115:23-117:18, 193:23-194:2, 199:7-17, 201:16-17, 205:7-12, 325:17-340:3, 372:18-373:2, 382:4-6. Aided by Plaintiffs' counsel, Dr. Blaivas later suggested that, because the title of Table 1 refers to "effectiveness," the table was only intended to identify long-term studies addressing efficacy of synthetic mesh devices and that some of the other studies were taken into account when calculating the 12.5% complication rate (as evidenced by the fact that they are cited in the article). *Id.* at 407:21-413:24; *see also id.* at 339:6-340:3. Aside from the fact that this explanation does not comport with Dr. Blaivas's admission that they should have been cited in the table, Dr. Blaivas has not explained—whether in the review article, his expert report, his deposition or anywhere else—how these omitted studies were taken into consideration when deriving the 12.5% calculation.[3]

In any event, any suggestion by Dr. Blaivas that TVT has a minimal 12.5% complication rate is inflated (and unreliable), because he and his co-authors took into account studies that are not specific to TVT Devices, but instead, the *entire universe* of synthetic mesh products, including prolapse devices and devices manufactured by Defendants' competitors. *See*, *e.g.*, Ex. H, Sept. 2015 Dep. 251:18-22; Ex. 4 thereto, pp. 4-21. As discussed in Dr. Blaivas's 2015 review article, there is ample undisputed evidence that the success and complication rates of synthetic

[3] Even under this explanation, the review article still makes no reference in any form or fashion to Serati's 10-year TVT follow-up study, as well as 11 other studies. Ex. H, Sept. 2015 Dep. 424:8-16; Ex. 12 thereto.

mesh products vary widely. *See, e.g.*, Ex. 4 to Sept. 2015 Dep. (Ex. H); Ex. H, Sept. 2015 Dep. 101:12-14, 143:4-144:9.

Moreover, as set forth Ethicon's brief supporting its motion to exclude Dr. Scott Guelcher's general opinions, the Prolene® mesh contained in TVT Devices includes unique antioxidant additives that studies have shown make it less susceptible to complications than the mesh in Ethicon's competitors' products.[4] Further, as acknowledged by Dr. Blaivas, the rate and severity of SUI mesh complications is less than the rate of prolapse mesh complications, and transobturator slings have a higher rate of certain complications than retropubic slings and a lower rate of other complications. Ex. H, Sept. 2015 Dep. 77:2-9, 313:18-22.

In fact, Dr. Blaivas's own review paper states that the Type I mesh in TVT Devices is "optimal" as compared to other mesh and has lower complication rates than Type II to IV meshes. Ex. 4 to Sept. 2015 Dep. (Ex. H), p. 11; Ex. H, Sept. 2015 Dep. 123:5-15, 124:8-11, 126:1-127:3, 143:4-144:9, 141:2-12. Yet, Dr. Blaivas lumps TVT Devices with all of these other mesh devices in projecting (apparently out of thin air) a 12.5% complication rate. Under these circumstances, Dr. Blaivas's study and other studies that at best simply measure the complication rates of *all* synthetic mesh are flawed and unreliable, and Ethicon should not be prejudiced by poorer outcomes of non-midurethral devices or its competitors' products.

2. Selective Choosing

Dr. Blaivas's aforementioned omission of several long-term studies in his review article illustrates his pattern of discounting contrary medical literature without adequate explanation. As another example, Dr. Blaivas was asked about a comprehensive meta-analysis performed by Novara and others comparing autologous slings with synthetic slings. Ex. 29 to Sept. 2015 Dep.

[4] In fact, Dr. Blaivas has conceded that he found PROLENE® sutures he has used in autologous slings to be biocompatible with his patients, and his 2015 review article noted that antioxidants retarded degradation. Ex. H, Sept. 2015 Dep. 42:17-44:21; Ex. 4 thereto at 17.

(Ex. H). Faced with that paper's report that randomized control trials demonstrated that autologous slings had a higher reoperation rate than synthetic slings, Dr. Blaivas responded that "I do not have any confidence that they – that they did the analysis correctly." *Id.* at 224-26; Ex. H, Sept. 2015 Dep. 276:5-21. Yet, when asked to explain the basis for his skepticism, Dr. Blaivas made conclusory, illogical and unsupported assertions that the paper had "contradictions," which he was unable to identify. *Id.* at 276:13-279:5; *see also id.* at 302:1-24.

In support of its findings about alleged TVT Device complications, Dr. Blaivas's 2015 review article cites a paper by Abbott and others. Ex. B, TVT Report at n. 14, 41; Ex. H, Sept. 2015 Dep. Ex. 21. The Abbott paper (which distinguished SUI sling mesh devices from prolapse device mesh devices) reported that "those women with complications after a sling-only procedure were treated more often with medical treatment first and *rarely* required surgical reintervention." *Id.* at 163.e6 (emphasis added). Although Dr. Blaivas agreed that this finding is "consistent with the literature," he nevertheless, "take[s] issue with it." Ex. H, Sept. 2015 Dep. 314:16-315:9. For grounds, Dr. Blaivas claimed to have read other literature that found differently, but he could not identify any such alleged. *Id.* at 315:16-316:12.

As this Court recently noted in *Winebarger,* 2015 WL 1887222, at *8, "[a]n expert's opinion may be unreliable if he fails to account for contrary scientific literature and instead "selectively [chooses] his support from the scientific landscape." (Citations omitted). Dr. Blaivas has achieved the conclusion that he wants to achieve by cherry-picking favorable portions of certain papers while arbitrarily rejecting unfavorable portions of those same papers. In the same manner, he has arbitrarily discounted other studies that do not comport with the opinions he would like to offer in this case. Because Dr. Blaivas's failure to account for this literature is not based on any sound scientific principles, his opinions are unreliable and should be excluded.

3. Flawed Assessment of Pain, Dyspareunia & Sexual Dysfunction Data

Dr. Blaivas's perception of TVT Device complications is also inconsistent with medical literature that he, himself, helped formulate. For instance, Dr. Blaivas's opinions about the rate of pain, dyspareunia, and sexual dysfunction associated with SUI surgical procedures is inconsistent with his own 2015 review article and the AUA guidelines. The AUA guidelines that Dr. Blaivas helped formulate based on an amalgamation of numerous studies reported that only 1% of all midurethral synthetic sling patients experience pain and 0% experience sexual dysfunction. Ex. H, Sept. 2015 Dep. 153:16-21, 158:12-159:8; Ex. L, Apx. A16. By comparison, the AUA reported that 10% of autologous sling patients report pain and that 8% report sexual dysfunction (with Burch complications slightly lower). *Id.*; Ex. H, Sept. 2015 Dep. 164:2-165:16.

Claiming that "I don't know how this occurred," Dr. Blaivas testified that "I'm confident that nobody on that committee would say that there is a zero incidence of sexual dysfunction and a 1 percent incidence of pain after midurethral sling." Ex. H, Sept. 2015 Dep. 161:24-162:14. Aside from the fact that it is impermissible for Dr. Blaivas to testify about what others supposedly "would say," Dr. Blaivas cannot reconcile such an assertion with the fact that *none* of the panelists referenced any disagreement with these figures in the AUA guidelines. Notably, the AUA guidelines explicitly offered the contributors the opportunity to connote that "[a]lthough this estimate is based on some published data, the panel believes the estimates are not consistent with their experience," and *no such connotation was placed* with respect to this data (although the connotation was made with respect to other data in the guidelines). *Id.* at 159:11-160:4, 163:6-164:1; Ex. L, Apx. A16.

Dr. Blaivas also responded that "I'm quite sure that . . . there was insufficient methodologies [sic] to come to those conclusions" and that "we lamented the fact that there were so few studies to make – to come to any reasonable conclusions." Ex. H, Sept. 2015 Dep. 158:22-24, 161:11-14. If he is correct, then *by his own acknowledgment*, there necessarily is insufficient methodology to support his own opinions about the risk of pain and sexual dysfunction associated with TVT Devices and other surgical alternatives. Further, Dr. Blaivas's own 2015 review article calculated that only 1.8% of retropubic mesh (like TVT) patients have pain more than six weeks postoperatively. Ex. H, Sept. 2015 Dep., Ex. 4, p. 5. When asked whether any of the studies indicated that the patients continued to have pain at six months or later postoperatively, Dr. Blaivas responded that "I could not find that information" with the exception of one study that he was unable to recall. Ex. H, Sept. 2015 Dep. 259:15-261:1.

4. Flawed Assessment of Erosion/Exposure/Extrusion Data

Dr. Blaivas acknowledged that the medical literature (including his own article) has shown that the rate of exposure for the mesh in TVT Devices is "low" and less than 2.5%. Ex. H, Sept. 2015 Dep. 172:13-173:11, 224:19-16, 296:12-297:1, 346:18-22; Ex. 4 thereto, p. 5. During his deposition, Dr. Blaivas was presented with the esteemed SGS review group's article detailing the results of a systematic review of randomized controlled trials for SUI procedures. Ex. H, Sept. 2015 Dep. 281:13-286:23; Ex. 20 thereto. Based on numerous studies assessing thousands of patients, the group found that the risk of exposure for retropubic synthetic slings (such as TVT) was 1.4%, as compared to 5.4% for autologous slings. *Id.* at 296:12-297:6; Ex. 20 thereto, p. 1.e7.

Dr. Blaivas was "incredulous" about this data during his deposition, but he could not offer an explanation other than that it was inconsistent with what he has personally encountered.

Ex. H, Sept. 2015 Dep. 297:20-299:15, 428:23-429:12, 432:11-15. Again, Dr. Blaivas's "fail[ure] to account for contrary scientific literature" renders his opinions unreliable. *Winebarger*, 2015 WL 1887222, at *8. Dr. Blaivas may not credibly distinguish these studies merely by stating that they do not comport with his personal experiences. *Id.* at *10; *Cisson v. C.R. Bard, Inc.*, 948 F. Supp. 2d 589, 606 (S.D. W. Va. 2013).

5. Flawed Assessment of Infection Data.

Dr. Blaivas's complication rate opinions also unreliably assume that TVT poses a heightened risk of infection. In his report, Dr. Blaivas suggests that TVT "should not have been designed for placement in a surgically contaminated field without proper animal and clinical studies," and that there is a heightened risk of infection. Ex. B, TVT Report at II.3, 29, 53. In support of this opinion, Dr. Blaivas, who admittedly is not an infectious disease expert (Ex. H, Sept. 2015 Dep. 60:17-20), cites literature that does not support, and in fact, refutes his opinion.

First, Dr. Blaivas cites a paper by Culligan and others, but that paper determined that *0* out of 23 patients implanted with TVT developed an infection. Ex. B, TVT Report at II.3 n.3; Ex. H, Sept. 2015 Dep. 62:3-12 and Ex. 2 thereto. Second, Dr. Blaivas cites a paper by Vollebregt and others that discusses *prolapse* mesh—not SUI mesh. Ex. B, TVT Report at II.3 n.4; Ex. H, Sept. 2015 Dep. 70:19-4 and Ex. 2 thereto. In fact, the very first page of the Vollebreght paper states that Type I mesh, such as TVT, shows "*the lowest risk of infection*," "has been shown *not* to be associated with a significant risk of mesh-related infection," "and "*is, therefore, widely used*." Ex. H, Sept. 2015 Dep. Ex. 2, p. 1; Sept. 2015 Dep. 71:5-72:7 (emphasis added). Dr. Blaivas's 2015 review paper estimated the risk of serious infection from synthetic slings to be miniscule. Ex. H, Sept. 2015 Dep., Ex. 4, p. 5; Sept. 2015 Dep. 75:3-77:1.

In fact, Dr. Blaivas stressed that he has qualified his opinions about infection with a "caveat" that Ethicon should have first conducted "proper animal and clinical studies," thus showing that, without such studies, Dr. Blaivas's opinions about infection are uncertain. Ex. B, TVT Report at II.3; Ex. H, Sept. 2015 Dep. 57:19-58:10. But this Court has previously determined that "[t]here is no indication in the record that Dr. Blaivas has any experience or knowledge on the appropriate testing a medical device manufacturer should undertake." *Huskey*, 29 F. Supp. 3d at 723. Finally, Dr. Blaivas acknowledged that infection is also a risk of the Burch and autologous sling procedures, and that TVT has certain comparative advantages in minimizing the risk of infection. Ex. H, Sept. 2015 Dep. 66:2-13, 230:20-231:4. For all of these reasons, Dr. Blaivas's opinions that TVT Devices pose a heightened risk of infection are woefully unreliable.

II. The Court should preclude Dr. Blaivas from testifying that traditional surgical approaches are a safer alternative to the devices at issue.[5]

Although Dr. Blaivas admits that TVT is as efficacious as (if not more efficacious than) alternative procedures for the surgical treatment of SUI, he claims that autologous slings are safer. Ex. H, Sept. 2015 Dep. 81:17-83:1, 103:21-22; Ex. B, TVT Report at II.20-23.[6] Dr. Blaivas also suggests that other repair procedures, such as anterior colporrhaphy, which sutures the vagina to bone in order to lift the urethra, are a safer alternative to Prolift. Ex. G, Prolift Report at 4, 13-15. As set forth below, these opinions should be excluded because they are irrelevant and unreliable.

[5] If the Court concurs with Defendants on this argument in Section II, it need not consider Sections III-V.

[6] Dr. Blaivas does not perform Burch colposuspension; he has acknowledged that it is not as effective as TVT and autologous slings; he has acknowledged that he is generally unfamiliar with data/literature concerning the Burch procedure; and he has not indicated that he would consider it to be a feasible alternative to TVT. Ex. H, Sept. 2015 Dep. 17:12-21, 20:7-10, 82:20-23, 150:12-15, 152:11-18, 165:11-16, 189:5-190:6, 211:16-23, 215:2-8.

A. Traditional surgical approaches are not a device, and therefore, irrelevant.[7]

Any alleged comparative benefits of traditional surgical approaches to treat SUI or POP are not even relevant to Plaintiffs' design defect claims, because those procedures are not medical devices. As set forth in Defendants' brief supporting their motion to exclude the general opinions of Daniel Elliott, M.D., any alleged comparative benefits of traditional surgical procedures are not even relevant to Plaintiffs' design defect claims, because those procedures are not medical devices.

B. Dr. Blaivas improperly bases his opinions about the benefits of autologous slings solely on his own unreliable personal experiences.

Even if Dr. Blaivas's opinions about autologous slings were relevant, they are inadmissible because they are unreliable. With rare exceptions, Dr. Blaivas only uses autologous fascia pubovaginal slings for the surgical treatment of SUI, and he has never implanted a TVT device. Ex. H, Sept. 2015 Dep. 14:19-24, 17:12-21, 25:9-17, 36:5-6.

In support of his statement that "serious complications do not occur or occur very rarely" with autologous slings, Dr. Blaivas cites one article that reports his own personal experiences. Ex. B, TVT Report at II.22; Ex. M[8] According to Dr. Blaivas, he has had great success with the manner by which he implants autologous slings, his patients have encountered few complications, and, "in the hands of good surgeons," autologous slings are as effective as TVT.

[7] This argument applies to the following Plaintiffs in which applicable state law requires a plaintiff to prove the availability of a feasible, safer alternative product: Babcock and Wolfe (N.Y.-- *Sita v. Danek Med., Inc.*, 43 F. Supp. 2d 245, 258 (E.D.N.Y. 1999); Barker, Durham & Quijano (Tex.-- *Hernandez v. Tokai Corp.*, 2 S.W.3d 251, 256, 258 (Tex. 1999)); Clayton & Ruebel (La.--La. Rev. Stat. § 9:2800.56; *Reeves v. AcroMed Corp*, 44 F.3d 300, 308 (5th Cir. 1995); Holzerland (Iowa-- *Daughetee v. Chr. Hansen, Inc.*, 960 F. Supp. 2d 849, 876 (N.D. Iowa 2013)); Johnson & Kivel (Minn.-- *Kapps v. Biosense Webster, Inc.*, 813 F. Supp. 2d 1128, 1161 (D. Minn. 2011)); Jones (Mich.--Mich. Comp. Laws § 600.2946(2); *BMW Croske of N. Am. Inc.*, 532 F.3d 511, 515-16 (6th Cir. 2008)); Kriz & Patterson (Ohio--OHIO REV. CODE § 2307.75(F); *McGrath v. Gen. Motors Corp.*, 26 F. App'x 506, 510 (6th Cir. 2002)); Phelps & Sacchetti (Md.--*Nissan Motor Co. Ltd. v. Nave*, 740 A.2d 102, 118 (Md. Ct. Spec. App. 1999); and Shultis (Wis.-- Wis. Stat. Ann. § 895.047(1)(a).

[8] Footnote No. 33 in Dr. Blaivas's report also references an article by Roberta Blandon, but that article deals with pelvic organ prolapse and does not address autologous sling complication rates. (Ex. N).

Ex. H, Sept. 2015 Dep. 213:22-214:3, 215:9-17, 264:15-20; Ex. B, TVT Report at II.20-23. When confronted with medical literature showing that the complication rates for autologous slings are comparable to and/or higher than synthetic sling patients, however, Dr. Blaivas could only respond that the data "does not comport with any experience I've had." Ex. H, Sept. 2015 Dep. 291:24-300:5.

It is utterly unreliable for Dr. Blaivas to base his comparison of synthetic slings with autologous slings on his own personal experiences with autologous slings.[9] Dr. Blaivas has not compared experiences of patients implanted with a TVT by Dr. Blaivas (there are none) with patients implanted with an autologous sling by Dr. Blaivas. Instead, he is making an "apples and oranges" comparison of the experiences of *other physicians*' synthetic sling patients solely with *his own* autologous sling patients. Complication rates of patients whom Dr. Blaivas implanted with an autologous sling are not representative of the complication rates for autologous sling patients throughout the country. Dr. Blaivas cannot personally perform all SUI surgeries in this country, and just because he may be a more skilled surgeon whose patients experience few complications does not mean that his personal experiences are representative of most surgeons who implant autologous slings. In fact, Dr. Blaivas has even written in a published piece that

> pubovaginal fascial sling for stress urinary incontinence has never achieved widespread popularity. We believe that the operation lacks popularity because the complication rate, particularly in the hands of inexperienced surgeons, is probably much higher than reported in the literature.

Ex. O.

Dr. Blaivas, indeed, has acknowledged that he does not know what percentage of surgeons use autologous slings, that other surgeons implant autologous slings in many different

[9] Although Dr. Blaivas suggests that his opinions are also premised on the notion that, had colleagues encountered complications, he would have heard about it (*see* Ex. H, Sept. 2015 Dep. 405:7-17), this is a far cry from reliable scientific methodology.

ways, that "few people do the surgery" the way that he performs it, that autologous sling patients of other surgeons likely have higher complication rates than his patients, and that he is unsure how common certain aspects of the procedure are done. Ex. H, Sept. 2015 Dep. 79:1-5, 105:14-19, 218:18-219:15, 221:16-222:23, 264:15-20, 300:10-15, 434:16-435:3. According to Dr. Blaivas, autologous sling surgery is "an operation where kind of everybody does it whatever way they want," as compared to synthetic sling surgery, which is "pretty consistent in its efficacy, surgical technique and the complication rates." *Id.* at 265:23-266:15.

Therefore, it is wholly speculative and improper for Dr. Blaivas to leap to the conclusion that the patients of other autologous sling surgeons in this country have experienced complication rates similar to his patients. In fact, Dr. Blaivas has acknowledged that the literature shows that other autologous sling patients generally have less favorable outcomes than Dr. Blaivas's patients. *See, e.g.*, Ex. H, Sept. 2015 Dep. 297:2-301:12, 306:19-23.

Moreover, Dr. Blaivas cannot be certain of his own patients' complication rates, because, in Dr. Blaivas's own words, "many, if not most, patients who experience complications do not return to their original implanting surgeons, contributing to a misperception among individual physicians that their outcomes are better than they, in fact, are." Ex. B, TVT Report at II.26.

Dr. Blaivas has also admitted that there are no reliable medical studies demonstrating that his personal success with autologous slings is consistent with the experiences of other surgeons. Dr. Blaivas testified that "I would want to see about a decade"-long study to make meaningful conclusions about SUI surgery options. Ex. H, Sept. 2015 Dep. 86:17-21. Dr. Blaivas, however, stated that he was unaware of *any* decade-long autologous sling studies. *Id.* at 86:22-88:2.[10] Nor is he aware of any randomized controlled trials that have assessed autologous slings based on a

[10] As set forth in Section I.B.1 above, there are many long-term TVT studies, many of which Dr. Blaivas has chosen to disregard.

duration of more than five years, and he has not published any of his own experiences with autologous slings involving a duration of more than five years. *Id.* at 91:3-10, 217:14-19.

When asked to "characterize the overall quality of evidence for autologous pubovaginal slings," Dr. Blaivas responded that "[i]n general, I would say *poor*." *Id.* at 97:20-98:5 (emphasis added).[11] *See also id.* at 290:13-291:4 (noting that there were only five autologous sling randomized controlled trials available to be addressed in a Society of Gynecologic Surgeons' ("SGS") systematic review, that "it's the best you can do, but they are hardly convincing to me," and that "it's unconvincing data to me"). Thus, just as Dr. Blaivas does not believe that there are reliable studies that refute his opinions about autologous slings, he has indicated that he does not believe that they are reliable studies that support his opinions.

Moreover, Dr. Blaivas is not sufficiently familiar with the available medical literature comparing autologous slings with TVT Devices and other synthetic slings. Although Dr. Blaivas acknowledged that the medical literature shows that autologous slings have a higher reoperation rate than synthetic slings, he stated that "I haven't looked at it in enough detail to see whether or not I think the methodology would support it." Ex. H, Sept. 2015 Dep. 280:24-281:11. *See also id.* at 105:11-14, 106:1-17 (stating that he believed that unidentified "current studies" would show that autologous slings did not lead to heightened complications, but cautioning that "I would need to see those papers to answer your question").

In support of his opinion that serious complications are much easier to treat than complications for synthetic mesh patients, Dr. Blaivas cites two papers: (a) his own 2011 report; and (b) an article by Blandon and others. Ex. B, TVT Report at II.22 & n. 33; Ex. M & N. The Blandon article does not even involve SUI surgeries, and instead, "describe[s] complications

[11] Plaintiffs' attempt to rehabilitate Dr. Blaivas on this point during his deposition fell flat. Ex. H, Sept. 2015 Dep. 403:16-404:24.

associated with the use of transvaginal mesh for treatment of *pelvic organ prolapse*." Ex. N, p. 523 (emphasis added).

Dr. Blaivas's 2011 article, however, only reports his personal experiences, and it states that "[t]his article provides an update on the surgical technique and long-term outcome of the full-length autologous rectus fascial sling in the treatment of women with *sphincteric incontinence*," not SUI. Ex. M, p. 7 (emphasis added).[12] In fact, Dr. Blaivas has acknowledged that the medical literature indicates that "those women with complications after a sling-only procedure were treated more often with medical treatment first and rarely required surgical reintervention." Ex. H, Sept. 2015 Dep. 314:16-315:9; Ex. 21 thereto, p. 163.e6.

In *Winebarger, supra*, this Court found that an expert "may not solely rely on his personal observations, especially when he seeks to provide broad opinions." 2015 WL 1887222, at *10. *See also Cisson*, 948 F. Supp. 2d at 606 (finding that an expert's calculation of complications rates based on his personal experiences "has no basis in any reliable methodology"); *In re Digitek Prods. Liab. Litig.*, 821 F. Supp. 2d 822, 839 (S.D. W. Va. 2011) (an expert's opinions are inadmissible as "inconsistent with good science" if he makes "overreaching or speculative conclusions . . . based upon overreaching or speculative methodologies"). Here, Dr. Blaivas seeks to offer broad opinions about autologous slings that are based on his personal experiences that are not corroborated by scientific studies. Accordingly, this does not satisfy the rigors of *Daubert* scrutiny and should be excluded.

C. Dr. Blaivas's opinions are grounded on his unreliable perception of TVT Device complication rates.

[12] Sphincteric incontinence, also known as instrinsic sphincter deficiency ("ISD"), is somewhat different than SUI. Whereas SUI entails leakage from such functions as laughing, coughing, as exercising, ISD is attributable to low leak pressure and leakage is not brought on by any particular activity. TVT Devices are designed to treat SUI, and autologous slings historically have been procedures used to treat ISD or severe SUI. Ex. O & P.

Dr. Blaivas's opinion that autologous slings are a preferable alternative to TVT Devices is also unreliable because it is premised on an unreliable assessment of TVT Device complication rates for the reasons set forth in Section I.B above.

III. The Court should preclude Dr. Blaivas from offering design opinions, such as testifying that other synthetic mesh devices offer safer alternatives.

In his reports, Dr. Blaivas asserts that "[t]he design of the Gynecare TVT [and other TVT Devices] is flawed." *See, e.g.*, Ex. B, TVT Report at II.31; Ex. C, TVT-O Report at II.43. When Dr. Blaivas was questioned about his design opinions during his deposition, Plaintiffs' counsel objected "to this whole line of questioning as beyond the scope," and Dr. Blaivas stated that "I hadn't ever thought about [sharing design opinions] in public." Ex. H, Sept. 2015 Dep. 129:4-12. Therefore, Plaintiffs may concede that Dr. Blaivas will not offer such opinions. In any event, the Court should otherwise exclude such opinions, because he is not qualified to offer them, he has not indicated with reasonable medical certainty that other mesh products are safer, and his opinions are unreliable.

A. Dr. Blaivas is not qualified.

There is nothing about Dr. Blaivas's background, training or experience that affords him expertise to provide design opinions. Dr. Blaivas has no expertise in biomaterials or polymer chemistry. Further, he has not conducted studies to compare the weight and pore size of TVT mesh to the mesh in other commercially available devices. He has never treated a patient for SUI or POP with a lighter weight larger pore mesh and cannot identify anyone else who ever has.

Further, with respect to TVT, Dr. Blaivas has never performed an analysis in which he "ascertain[ed] the number and body of literature on, specifically, the TVT," and he has not reviewed any literature or conducted any other evaluation to compare TVT with other mesh products. Ex. H, Sept. 2015 Dep. 100:7-14, 142:7-16, 144:14-16. As Dr. Blaivas candidly

admitted: "Unfortunately, I just didn't look at the literature comparing TVTs to other [mesh] products." *Id.* at 142:13-16. Therefore, there is no reliable basis for him to compare TVT with other mesh devices at trial.

This Court has repeatedly found that "Dr. Blaivas lacks the 'knowledge, skill, experience, training or education' as to product design that *Federal Rule of Evidence 702* requires" and that his experience removing mesh devices and observing complications does not render him qualified to provide opinions concerning design. *Tyree v. Boston Scientific Corp.*, 54 F. Supp. 3d 501, 561 (S.D. W. Va. 2014); *Wilkerson v. Boston Scientific Corp.*, 2015 WL 2087048, at *15 (S.D. W. Va. May 5, 2015). Dr. Blaivas has not had any experiences since those rulings that would suddenly make him competent to opine about product design.

B. Dr. Blaivas's weight/pore size opinions are unreliable.

In his reports, Dr. Blaivas suggests that devices with lighter weight, larger pore-sized mesh are preferable alternatives. Ex. B, TVT Report at II.51-52, 54; Ex. G, Prolift Report at 3-4. Yet, Dr. Blaivas's suggestions about alternative mesh are inconsistent with his own *2015* review article. Ex. H, Sept. 2015 Dep., Ex. 4.

In that article, Dr. Blaivas stated that Type I mesh, which is knitted monofilament, macro-porous mesh is considered to be the "*optimal*" mid-urethral sling "owing to its large pore size." *Id.* at 11; Ex. H, Sept. 2015 Dep. 123:5-15 (emphasis added). Dr. Blaivas has acknowledged that the Prolene mesh in TVT Devices is a knitted monofilament, macro-porous Type I mesh, that Type I mesh is the "preferred" material, and that it is "well documented" that Type I mesh has higher cure rates and lower complication rates than other meshes. Ex. H, Sept. 2015 Dep. 124:8-11, 126:1-127:3, 143:4-144:9, 141:2-12.

Dr. Blaivas conceded that he is uncertain whether meshes that are lighter and more macroporous are preferable, stating that there is not "enough data" to draw "meaningful conclusions." Ex. H, Sept. 2015 Dep. 124:16-125:14, 141:18-142:5. He could not identify any synthetic sling on the market that has a lower rate of scar contraction and a lower rate of inflammation than TVT, and he stated that "[t]he methodology is not adequate to make those conclusions, in my judgment." *Id.* at 144:10-145:7. For the same reasons set forth in Section I.B above, Dr. Blaivas's opinions about alternative synthethic mesh devices are simply unreliable.

A fundamental logical flaw and failure of proof behind Dr. Blaivas's opinions about pore size and weight is demonstrated in federal judge Ron Clark's opinion in *Conklin v. Novartis Pharmas. Corp*, 2012 WL 4127295 (E.D. Texas 2012). Judge Clark in an MDL case found that an expert could not opine about an allegedly safer alternative design as required by Texas law because there was no evidence as to the alternative's utility. The court illustrated this by setting out the expert's premises and conclusions:

> **Premise:** Studies show that a certain regimen of Zometa helps treat cancer-related bone conditions, but may cause [bone disease]
>
> **Premise:** Other studies show that less Zometa will result in less [bone disease].
>
> **Conclusion:** A regimen using less Zometa will help treat cancer-related bone conditions.
>
> This is a classic logical fallacy—an irrelevant conclusion.

Id. at *9. The court found an impermissible "analytical gap," because there was no evidence that reducing the dosage would not only reduce the side effect but would "also be effective at fighting cancer-related diseases." *Id*. at *10. *See also In re AlloDerm Litigation*, Case Code 295, N.J. Superior Court of Middlesex County (Aug. 14, 2015), attached as Ex. F, at p. 22 (rejecting challenge to hernia repair product because plaintiffs failed to "prove with empirical evidence or

reliable data that the alternative is actually safer and there was evidence it was safer at the time of manufacture").

Here, the same analytical gap exists. Dr. Blaivas has suggested that the mesh in the devices at issue would have less inflammation if made of larger pore, lighter weight mesh. But Dr. Blaivas points to no studies, testing, or other scientific evidence whatsoever that these devices would have been equally effective as a treatment for SUI or POP if the mesh had those characteristics. Nor does Dr. Blaivas point to any evidence that, had the mesh had such characteristics, there would not be an increased risk of other adverse events. Like the opinion stricken in *Conklin*, Dr. Blaivas's opinions are supported by nothing more than the "naked conclusion" of the expert. That is not enough.

In fact, when asked how he would change the design of TVT to reduce the risk of inflammation, erosion, and contraction, Dr. Blaivas responded: "That's for them to figure out." Ex. H, Sept. 2015 Dep. 140:19-141:1. In *Huskey*, Dr. Pandit, in similarly criticizing TVT-O's design, testified that "I don't want to give Ethicon ideas on what they should be doing." 29 F. Supp. 3d at 712. This Court found that,"[w]ithout an explanation from [the expert] about [what . . .] would be suitable alternative designs, these opinions are unreliable and are EXCLUDED." *Id.* As with *Huskey*, the Court should preclude Dr. Blaivas from making vague suggestions that any other synthetic mesh products are safer alternatives to TVT, given Dr. Blaivas's: (a) lack of qualifications; (b) unwillingness to commit to such an opinion within a reasonable degree of medical certainty; (c) acknowledgment that there simply is not "enough data" from which to draw any "meaningful conclusions"; and (d) admission that he did not compare the mesh in TVT with the mesh in other synthetic mesh devices.

C. Dr. Blaivas's opinions about the cutting of TVT Device mesh are unreliable.

Dr. Blaivas suggests that either laser-cut mesh or mechanically-cut mesh is preferable, apparently depending on which type of mesh was not implanted in Plaintiff. Ex. B, TVT Report at II.44-50. Any suggestion that either laser-cut mesh or mechanically-cut mesh provides a safer alternative lacks a reliable, scientific foundation. Nor has he compared mechanically-cut mesh with laser-cut mesh, and he cites no scientific studies or experiences that support his opinions about the cutting of mesh. For the same reasons set forth in Section III.B above, these opinions are improper.

Moreover, Dr. Blaivas has been playing both sides of the fence on this issue. Dr. Blaivas cannot have it both ways. He cannot simultaneously argue that mechanically-cut mesh is less safe than laser cut-mesh and that laser-cut mesh is less safe than mechanically-cut mesh. If the Court permits Dr. Blaivas to offer opinion testimony critiquing mechanically-cut mesh, it should preclude him from referencing laser-cut mesh as a viable alternative design, and vice versa. *See Huskey*, 29 F. Supp. 3d at 712-13 (precluding expert from testifying that laser-cut mesh was preferable given vague, noncommittal testimony).

D. Dr. Blaivas's opinions about TVT implantation design are unreliable.

Dr. Blaivas believes Ethicon should have designed TVT for a "top to bottom" implantation approach, rather than a "bottom to top" approach, due to a risk of organ perforation. Ex. B, TVT Report at II.14-15; Ex. H, Sept. 2015 Dep. 131:21-132:18.

Yet, Dr. Blaivas's criticism is completely refuted by the fact that Ethicon, unbeknownst to Dr. Blaivas, marketed a "top to bottom" TVT device. Ex. Q, Elliott 9/26/15 Dep. 51:13-17, 78:22-23; Ex. H, Blaivas Sept. 2015 Dep. 136:4-8. Regardless, Dr. Blaivas could not cite any data to support his opinion that a "top to bottom" approach leads to fewer complications, and he was unaware of any randomized control trials that supports his opinion. *Id.* at 136:9-18.

In fact, a Cochrane study upon which Dr. Blaivas has relied actually concluded that the "top to bottom" approach advocated by Dr. Blaivas was less effective and had more complications than the TVT "bottom to top" approach. *Id.* at 136:22-140:18; Ex. 5 thereto. Dr. Blaivas has relied on another study which concluded that retropubic trocar passage does not have a statistically significant increased odds ratio risk. Ex. H, Sept. 2015 Dep. 243:13-244:20; Ex. 18 thereto, p. 1169. Dr. Blaivas, thus, has selectively chosen information from studies and has not offered any reliable explanation for his failure to credit contrary evidence. *Winebarger*, 2015 WL 1887222, at *8.

Dr. Blaivas has also criticized the design of the surgical trocars as "too big, too thick and too pointed" and claimed that the "blind passage" technique of TVT implantation is such that it also heightens the risk of bladder and urethra perforation. Ex. B, TVT Report at II.13-14, Ex. H, Sept. 2015 Dep. 127:23-128:14, 132:19-133:10. Dr. Blaivas, however, stated that "I don't think I can say in words very succinctly what needs to be done," as it relates to the trocar design. *Id.* at 128:23-129:1. In his report, Dr. Blaivas cites only two articles in support of the notion that "[t]here is ample evidence in the literature that it is very common for the trocars to inadvertently puncture the bladder or urethra during trocar passage." Ex. B, TVT Report at II.13, citing Ex. R&S hereto. One of these articles is based on laparoscopic surgery, which has *nothing* to do with synthetic mesh device implantation. Ex. R; Ex. H, Sept. 2015 Dep. 148:13-149:12. The other article relates to the transobturator approach rather than the TVT approach (which uses retropubic passage), and in any event, did not show a statistically significant distinction. Ex. S.

E. Dr. Blaivas's opinions about TVT-O and TVT-Abbrevo are unreliable.

In Section II.5 of his TVT-O report, Dr. Blaivas claims that TVT-O increases the risk of certain injuries and in Section II.32 of his TVT-Abbrevo report, Dr. Blaivas states that "the

shorter length of the laser cut mesh in the TVT Abbrevo leads to more complications." Ex. C&F. Dr. Blaivas cites no studies in support of these conclusory statements. His later assertion is based solely on one internal Ethicon document, which lends no support to the assertion. Ex.T, ETH.MESH.09911296. Given the utter lack of methodology in support of these opinions, the Court should reject them as unreliable.

IV. The Court should limit Dr. Blaivas's biomaterials opinions, such as testimony about alleged mesh degradation, shrinkage, and other deformations.

In his reports, Dr. Blaivas claims that the polypropylene mesh in the devices at issue is incompatible with the human body, but he fails to cite a single study in support. Ex. B, TVT Report at II.59; Ex. G, Prolift Report at 3, 7. He also asserts that degradation of the mesh occurs as a consequence of particle loss and other alleged defects in the mesh and that the mesh shrinks, curls, ropes, stiffens and undergoes other deformations *in vivo.* Ex. B, TVT Report at II.55-57, 60. The Court should exclude these opinions because Dr. Blaivas is unqualified and his opinions are unreliable.

A. Dr. Blaivas is not qualified.

Because he is not a bio/polymer chemist and has no background in polymer science, Dr. Blaivas is not competent to testify about issues involving molecular weight, tensile strength and oxidative degradation. Dr. Blaivas has not performed any testing on polypropylene meshes (such as shrinkage) and has deferred to others. Ex. U, 1/30/14 Dep. 458:12-459:8, 465:8-466:2, 482:2-484:20. In fact, he has acknowledged that "the biochemistry and stuff was over my head" and that "I think experts that are more expert at this than me should look into this in more depth." *Id.* at 482:12-13, 484:17-19. *See also* Ex. V, 8/13/15 Dep. 196:17-19, 212:17-23, 274:24 - 276:19 (conceding lack of expertise in this area and deferring degradation questions to a pathologist or biomaterials expert).

On at least two different occasions, this Court has precluded Dr. Blaivas from testifying about mesh degradation and shrinkage because his report did not disclose any experience with these alleged issues. *See Tyree*, 54 F. Supp. 3d at 562; *Huskey*, 29 F. Supp. 3d at 722. Once again, Dr. Blaivas's expert report in this case does not set forth any personal experience to demonstrate that he is competent to testify about these biomaterials issues, and he has conceded that he is not qualified. Accordingly, the Court should exclude these opinions.

B. Dr. Blaivas's opinions are unreliable.

Even if Plaintiffs were able to show that Dr. Blaivas is qualified to testify on these matters, his opinions are unreliable. In support of his blanket statements, Dr. Blaivas has merely regurgitated studies that are misleading and irrelevant. Dr. Blaivas's reliance on these studies is misplaced, and his conclusory opinions about degradation are unreliable and speculative. For instance, the studies cited in Dr. Blaivas's TVT report are geared toward generic polypropylene, rather than the TVT mesh at issue that contains Prolene mesh. Ex. B, TVT Report at II.56 & 57. Dr. Blaivas's reliance list does not reference any scientifically legitimate efforts to establish that Prolene is subject to the same degradation issues as generic polypropylene. *See* Defendants' brief supporting their motion to exclude Dr. Guelcher general opinions, filed contemporaneously with this brief. As such, Dr. Blaivas's conclusory opinions are inadmissible speculation. *See In re Digitek*, 821 F. Supp. 2d at 839 (an expert's opinions are "inconsistent with good science" if he makes "overreaching or speculative conclusions . . . based upon overreaching or speculative methodologies").

Further, the basis for Dr. Blaivas's contention that polypropylene is incompatible with the human body is an MSDS for "polypropylene resin" – not polypropylene and certainly not Prolene, which is a specially formulated form of polypropylene with antioxidants added. Ex. B,

TVT Report at II.59; Ex. W, ETH.MESH.02026591. Dr. Blaivas has performed no methodological analysis of this claim.

V. The Court should preclude testimony about inflammatory alleged conditions.

As set forth in Defendants' motion in limine, the Court should preclude Dr. Blaivas from testifying about cancer and other alleged complications that a particular Plaintiff has not suffered or in which a competent physician has not testified that a Plaintiff likely will face in the future, such as death and cancer. *See* Ex. B, TVT Report at II.3-7, 21, 24, 58. As this Court has noted, "[e]vidence of complications that the plaintiff did not experience is irrelevant and lacking in probative value." Ex. X, *Bellew v. Ethicon, Inc*., No. 2:13-cv-22473, Order at 20 (S.D. W. Va. Nov. 20, 2014).

Along these lines, the Court should also preclude Dr. Blaivas from testifying about the alleged existence of "Chronic Mesh Pain Syndrome." *See* Ex. B, TVT Report at II.7. Although Dr. Blaivas claims that such a condition is "described in the medical literature" (*id.*), he cites only one article that has used that term. Ex. Y. Dr. Blaivas acknowledged that he is unaware of chronic mesh pain syndrome being recognized as a diagnostic code for billing purposes. Ex. H, Blaivas Sept. 2015 Dep. 308:10-16. Plainly, this alleged syndrome is not generally accepted in the medical profession, and it has negative connotations that would prejudice Defendants. As this Court has cautioned, Dr. Blaivas should not be allowed to apply to his testimony standards different from those used in his medical practice. *Wilkerson*, 2015 WL 2087048, at *15.

Similarly, the Court should preclude Dr. Blaivas from testifying about an "increasing number of 'mesh cripples'" or about "Meshology." *See* Ex. B, TVT Report at II.10. Such terms are highly inflammatory and prejudicial, and the number of individuals alleged to have sustained mesh complications is irrelevant to these proceedings. In *Huskey*, this Court precluded Dr. Blaivas from testifying about "mesh cripples," finding that such testimony is irrelevant and that

"[w]hether future patients may face increasing rates of mesh-related complications will not help the jury decide the issues in this case." 29 F. Supp. 3d at 720-21. The Court should apply that ruling to this case.

VI. The Court should exclude Dr. Blaivas's product warning opinions.

Dr. Blaivas makes a number of criticisms of Ethicon's alleged lack of warnings, including in its IFUs. Ex. B, TVT Report at II.29-34; Ex. G, Prolift Report at 3, 11-12. Although this Court determined in *Huskey* that Dr. Blaivas was competent to testify about warnings, 29 F. Supp. 3d at 719, Dr. Blaivas has subsequently conceded that this is beyond his expertise

> Q. Do you consider yourself an expert in developing warnings and labels for medical devices?
>
> A. I do not.

Ex. V, 8/13/15 Dep. 316:19-22 (emphasis added). Dr. Blaivas also acknowledged that he is unfamiliar with regulations governing warnings for medical devices. *Id.* at 316:12-317:1. Relying on very similar admissions, this Court has determined that another pelvic surgeon, Dr. Bob Shull, is not qualified to testify about product warnings. *Cisson*, 948 F. Supp. 2d at 611.

This is not just a technical objection. Ethicon wrote its warnings, as the law contemplates, taking into account that the devices would be implanted by surgeons trained in SUI or POP surgery. There is no duty to warn those surgeons of adverse events about which they already know. Dr. Blaivas admits that "serious mesh complications" are well known, *Huskey*, 29 F. Supp. 3d at 721, but nevertheless claims that Ethicon erred by not warning about them. Because he has no warnings training, his testimony rests on the wrong legal standard.

Further, Dr. Blaivas's criticisms of Ethicon's IFUs demonstrates his lack of credentials. He faults the IFUs for not mentioning the "severity" of the potential adverse events and because

they list potential adverse events "with a kind of equanimity that minimizes the impact on patients and conveys to the doctor the impression that although these things might occur, they are very rare." Ex. B, TVT Report at II.32. Courts have routinely found that a manufacturer's duty to warn does not include providing incidence, severity, and frequency rates of a particular adverse event. *See, e.g., Smith ex rel. v. Wyeth Labs. Inc.*, 1986 WL 720792, at *9-10 (S.D. W. Va. Aug. 21, 1986) (noting that "[t]he plaintiff cites no authority for the proposition that a drug manufacturer has a duty to warn prescribing physicians of the rate of adverse reactions," and that "[a]s a practical matter, this would be extremely difficult, perhaps impossible").

VII. The Court should not allow Dr. Blaivas to testify about testing.

According to Dr. Blaivas, Ethicon should not have designed TVT for placement in a contaminated field or for permanent implantation in the human body "without proper animal and clinical studies." Ex. G, Prolift Report at 6; Ex. B, TVT Report at II.3. He also speculates that "[a]ppropriate and unbiased clinical testing, if performed, would have shown the problems and complications associated with synthetic slings, like the Gynecare TVT." *Id.* at II.36. The Court should exclude these opinions, because the opinions are irrelevant and Dr. Blaivas is not competent to testify about the level of testing that a manufacturer, such as Ethicon, should have performed.

A lack of testing or a flaw in the design process is not, standing alone, a design defect. *See, e.g., Green v. General Motors Corp.*, 310 N.J. Super. 507, 529 (App. Div. 1998) ("[A] product that is not defective and has not been tested at all remains free of a defect"). The "failure to test" claim here should be seen for what it is—a transparent attempt to shift the burden to the *defendant* to prove the absence of the defect when the plaintiff cannot carry her burden to prove the existence of a defect.

Even if the degree of testing were relevant, there is nothing in Blaivas's background that would provide him with specialized knowledge about the testing that Defendants or other medical device manufacturers supposedly should have performed. In *Huskey*, the Court precluded Dr. Blaivas from offering these same opinions, finding that "[t]here is no indication in the record that Dr. Blaivas has any experience or knowledge on the appropriate testing a medical device manufacturer should undertake." *Huskey*, 29 F. Supp. 3d at 723. Furthermore, Dr. Blaivas may only speculate as to what hypothetical testing would have revealed. Aside from the fact that Dr. Blaivas does not set forth a proper foundation to show that prior clinical testing is unbiased, Dr. Blaivas does not say that he performed any testing, nor does he identify any third-party testing that he claims to be unbiased. Therefore, it is sheer, unreliable speculation what other hypothetical testing would have revealed.

VIII. The Court should preclude Dr. Blaivas from offering certain unreliable opinions suggesting bias, "industry manipulation," and collusion.

Dr. Blaivas makes broad statements in his report that the medical literature concerning TVT is "seriously flawed," due to alleged bias, "industry manipulation of data," and other alleged factors and that "Ethicon colluded with" other medical device manufacturers "to influence reimbursement for mesh procedures." Ex. G, Prolift Report at 14, 16; Ex. B, TVT Report at II.37, 39.

Dr. Blaivas does not identify any support whatsoever for his collusion and "industry manipulation" accusations. *See also id.* at II.41 (stating in conclusory fashion that professional societies that have endorsed the products are biased). Other statements are not supported by Dr. Blaivas's citations, such as his assertion that Ethicon has contracts with unidentified medical literature authors that "often contain language that prevents company consultants from reporting or discussing device complications without written company approval" *Id.* at II.40 (citing Ex. K).

In any event, Dr. Blaivas has no expert qualifications to testify about the potential bias that a financial incentive may play in medical research. He sets forth no methodology and simply provides a narrative summary of events.

IX. The Court should not allow other opinions beyond Dr. Blaivas's expertise and/or that are otherwise improper.

Dr. Blaivas's reports include statements about Ethicon's alleged knowledge and conduct. This Court has consistently found that experts in this MDL may not testify about device manufacturers' "knowledge, state of mind, alleged bad acts, failures to act, and corporate conduct and ethics." *Cisson v. C.R. Bard, Inc.*, 948 F. Supp. 2d 589, 611 (S.D. W. Va. 2013); *Huskey*, 29 F. Supp. 3d at 702-03. Dr. Blaivas's report also includes marketing opinions. *See, e.g.*, Ex.G, Prolift Report at 4 ("Ethicon marketed these products to inadequately trained physicians"); *id.* at 15 ("[M]esh kits were marketed based on perceived high failure rates"). As this Court has concluded, Dr. Blaivas is not competent to offer opinions about Ethicon's alleged marketing of its products. *See Huskey*, 29 F. Supp. 3d at 723.

The Court should similarly find that Ethicon may reserve for trial objections to Dr. Blaivas's testimony that are based merely on a narrative summary of Ethicon documents. *See, e.g., Hershberger v. Ethicon Endo-Surgery, Inc.*, 2012 WL 524442, at *8 (S.D. W. Va. Feb. 15, 2012) (excluding expert testimony based on defendant's corporate documents); *Hines v. Wyeth*, No. 2:04-0690, 2011 WL 2680842, at *5 (S.D. W. Va. July 8, 2011) (excluding expert testimony in part because it "merely regurgitates factual information that is better presented directly to the jury rather than through the testimony of an expert witness").

CONCLUSION

For the foregoing reasons, the Court should limit Dr. Blaivas's general opinions consistent with the above.

Respectfully Submitted,

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IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

IN RE: ETHICON, INC. PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	**Master File No. 2:12-MD-02327** **MDL No. 2327**
THIS DOCUMENT RELATES TO ETHICON WAVE 1 CASES	**JOSEPH R. GOODWIN** **U.S. DISTRICT JUDGE**

CERTIFICATE OF SERVICE

I, Christy D. Jones, certify that on April 21, 2016, I electronically filed the foregoing document with the Clerk of the Court using the CM/ECF system which will send notification of such filing to the CM/ECF participants registered to receive service in this MDL.

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